STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
	39C0001333	A. BLDG: 00 B. WING:	04/07/2023

NAME OF PROVIDER OR SUPPLIER:	STREET ADDRESS, CITY, STATE, ZIP CODE:
AZURA SURGERY CENTER SOUTH PHILADELPHIA	2412 WEST PASSYUNK AVENUE PHILADELPHIA, PA 19145

STATE LICENSE NUMBER: **24741501**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE	(X5) COMPLETE DATE
S 0000	INITIAL COMMENT This report is the result of a State licensure survey conducted on April 6 and 7, 2023, at Azura Surgery Center South Philadelphia. It was determined the facility was not in compliance with the requirements of the Pennsylvania Department of Health's Rules and Regulations for Ambulatory Care Facilities, Annex A, Title 28, Part IV, Subparts A and F, Chapters 551-573, November 1999.	S 0000		
S 0043	51.31 Exceptions - Principle 51.31. Principle The Department may grant exceptions to this part when the policy and objectives contained therein are otherwise met, or when compliance would create an unreasonable hardship and an exception would not impair or endanger the health, safety or welfare of a patient or resident. No exceptions or departures from this part will be granted if compliance with the requirement is provided for by statute. This REGULATION is not met as evidenced by:	S 0043	An approved Plan of Correction is not on file.	Completion Date: Status: **NO POC** Date:

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S 0043	Continued from page 1	S 0043		

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S 0043	Continued from page 2 Based on a review of facility documents and interview with staff (EMP), it was determined the facility failed to comply with the required criteria as stated in the exception granted by the Department for 28 Pa Code § 569.35(7), relating to the requirement that only nonflammable agents may be present in the surgical suite. The facility failed to ensure all staff involved in the use of surgical skin preparations that contain combustible agents participated in annual mandatory education for eight of 11 credential files (CF2, CF5, CF6, CF7, CF8, CF9, CF10, CF11) and one of 11 personnel files reviewed (PF5). Findings include: A review on April 6, 2023, of a letter from the Department dated June 8, 2017, revealed "The Department of Health is in receipt of your request for an exception to 28 Pa. Code 569.35(7), relating to the requirement that only nonflammable agents may be present in the surgical suite. You have completed the process established by the	S 0043		

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S 0043	Continued from page 3 Department for requesting an exception to this regulation and agreed to the following: ... The facility shall institute annual mandatory education provided to all staff, including the physician staff, involved in the use of surgical skin preparations that contain combustible agents. The content of the education provided and documentation of same will be reviewed by the Department during survey activity." A review on April 6, 2023, of facility documents revealed six physicians, two certified registered nurse anesthetists (CRNA) and one Radiology Technician had not completed the annual mandatory education for the use of surgical skin preparations that contain combustible agents/explosive hazards. An interview conducted on April 6, 2023, at 12:13 PM with EMP1 confirmed CF2, CF5, CF6, CF7, CF8, CF9, CF10, CF11 and PF5 actively worked at the facility and had not completed the annual mandatory education for the use of surgical skin preparations that contain combustible agents/explosive hazards.	S 0043		

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S 0043	Continued from page 4	S 0043		
S 033A	553.3 (1) Governing Body Responsibilities 553.3 Governing Body responsibilities include: (1) Conforming to all applicable Federal, State, and local laws. This REGULATION is not met as evidenced by:	S 033A	An approved Plan of Correction is not on file.	Completion Date: Status: **NO POC** Date:

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S 033A	Continued from page 5 Based on a review of the Department of Health (Department) database, facility documents, medical records (MR) and interview with staff (EMP), it was determined the facility was not in compliance with the following State Law. The Azura Surgery Center South Philadelphia was not in compliance with the following State law related to Act 13 2002, Medical Care Availability and Reduction of Error (MCARE), 40 P.S. § 1303.313 Section 313. Medical facility reports and notifications. (a) Serious event reports.--A medical facility shall report the occurrence of a serious event to the department and the authority within 24 hours of the medical facility's confirmation of the occurrence of the serious event. The report to the department and the authority shall be in the form and manner prescribed by the authority in consultation with the department and shall not include the name of any patient or any other identifiable individual information. (b) Incident reports.--A medical facility shall report the occurrence of an incident to the authority in a form and manner prescribed by the	S 033A		

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S 033A	Continued from page 6 authority and shall not include the name of any patient or any other identifiable individual information. (c) Infrastructure failure reports.--A medical facility shall report the occurrence of an infrastructure failure to the department within 24 hours of the medical facility's confirmation of the occurrence or discovery of the infrastructure failure. The report to the department shall be in the form and manner prescribed by the department. This is not met as evidenced by: Based on review of the Department's database, facility documents, medical records (MR) and interview with staff (EMP), it was determined that the facility failed to report serious events to the Department and the authority in four of four medical records reviewed (MR1, MR2, MR3 and MR5). Findings include: A review of the facility document "Pennsylvania (PA) Patient Safety Plan" dated February 6, 2021,	S 033A		

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S 033A	Continued from page 7 revealed "Purpose. For the purpose of improving the health and safety of patients. The PA Act 13 Patient Safety Plan (hereinafter referred to as the 'Plan') is to maintain and improve patient safety within the company. Administration, medical staff, managers and associates support the Plan. The Plan will implement the components of PA Act 13, as interpreted (and) put into regulations by the Pennsylvania Department of Health. Definitions. ... Serious Event: An event, occurrence, or situation involving the clinical care of a patient within the company that results in death or compromises patient safety and results in unanticipated injury requiring the delivery of additional health care services to the patient. ... Procedure ... 4. b. ... The Serious Event must be reported to the Pennsylvania Department of Health in accordance with established Rules and Regulations no later than 24 hours after discovery of serious event." A review on April 6, 2023, of the Department's database revealed no documentation of reports of Serious Events for MR1, MR2, MR3 and MR5.	S 033A		

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S 033A	Continued from page 8 A review on April 6, 2023, of MR1, admitted January 19, 2023, for an angioplasty with stent placement procedure under monitored anesthesia care (MAC) revealed the patient was treated for a suspected intravenous (IV) contrast allergic reaction during the procedure and was subsequently transferred to a hospital emergency department for further care. A review on April 6, 2023, of MR2, admitted March 13, 2023, for a thrombectomy procedure under monitored anesthesia care (MAC) revealed the patient developed a low oxygen saturation with electrocardiogram (ECG) changes after the procedure and was subsequently transferred to a hospital emergency department for further care. A review on April 6, 2023, of MR3, admitted March 15, 2023, for a fistulagram procedure under monitored anesthesia care (MAC) revealed the patient was treated for a suspected intravenous (IV) contrast allergic reaction during the procedure and	S 033A		

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S 033A	Continued from page 9 was subsequently transferred to a hospital emergency department for further care. A review on April 6, 2023, of MR5, admitted September 5, 2022, for a thrombectomy procedure under monitored anesthesia care (MAC) revealed the patient was treated for an increased heart rate with decreased oxygen saturation during the procedure and was subsequently transferred to a hospital emergency department for further care. An interview conducted on April 6, 2023, at 12:28 PM with EMP1, EMP2 and EMP3 confirmed the events for MR1, MR2, MR3 and MR5 were not reported to the Department and the authority as Serious Events.	S 033A		
S 312Q	553.12 (b)(16) Implementation 553.12 (b) The following are the minimal provisions for the patient's bill of rights: (16) When an emergency occurs and a patient is transferred to another facility, the responsible person shall be notified. The	S 312Q	An approved Plan of Correction is not on file.	Completion Date: Status: **NO POC** Date:

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
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S 312Q	Continued from page 10 institution to which the patient is to be transferred shall be notified prior to the patient's transfer. This REGULATION is not met as evidenced by:	S 312Q		

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S 312Q	Continued from page 11 Based on a review of facility policy, medical records (MR) and interview with staff (EMP), it was determined the facility failed to notify the responsible person prior to transfer to another facility for additional care services in two of five medical records reviewed (MR1 and MR5). Findings include: Review of the facility's "Patient Rights and Responsibilities-PA," published February 6, 2021, revealed "Purpose To establish a process whereby patients will be notified of their rights. ... Contents of Notice ... 23. When an emergency occurs and a patient is transferred to another facility, the responsible person shall be notified. The institution to which the patient is to be transferred shall be notified prior to the patient ' s transfer. ..." A review of facility policy "Emergency Transfer of Patients" dated February 7, 2021, revealed "Policy. The Center must have an effective procedure for the immediate transfer, to a hospital, of patients	S 312Q		

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S 312Q	Continued from page 12 requiring emergency medical care beyond the capabilities of the Center. Patient transfers will occur in an efficient, medically appropriate, and safe manner pursuant to all laws and regulations affecting the transfer of patients between the Center and the nearest, most appropriate local hospital, since a delay in transfer could affect the patient's health." Further review revealed a requirement to notify the responsible person prior to transfer to another facility for additional care services was not included in the facility policy. A review on April 6, 2023, of MR1, admitted January 19, 2023, for an angioplasty with stent placement procedure under monitored anesthesia care (MAC) revealed the patient was treated for a suspected intravenous (IV) contrast allergic reaction during the procedure and was transferred to a hospital emergency department for further care. There was no documentation the person identified as the responsible person was notified of the patient's transfer.	S 312Q		

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S 312Q	Continued from page 13 A review on April 6, 2023, of MR5, admitted September 5, 2022, for a thrombectomy procedure under monitored anesthesia care (MAC) revealed the patient was treated for an increased heart rate with decreased oxygen saturation during the procedure and was transferred to a hospital emergency department for further care. There was no documentation the person identified as the responsible person was notified of the patient's transfer. An interview conducted on April 6, 2023, at 3:42 PM confirmed there was no documentation the person identified as the responsible person was notified of the patient's transfer.	S 312Q		
S 552E	555.22 (e) Surgical Services - Preoperative 555.22 Pre-operative Care (e) Prior to the administration of anesthesia, it is the responsibility of the primary operating surgeon and the person administrating anesthesia to properly identify the patient and the procedure to be performed and to document this identification in the patient's medical record. This	S 552E	An approved Plan of Correction is not on file.	Completion Date: Status: **NO POC** Date:

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S 552E	Continued from page 14 procedure shall be in written policies designating the mechanism to be used to identify each surgical patient. This REGULATION is not met as evidenced by:	S 552E		

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S 552E	Continued from page 15 Based on a review of facility policy, medical records (MR) and interview with staff (EMP), it was determined the facility failed to ensure the anesthesia provider documented the identification of the patient prior to the administration of anesthesia in four of four medical records reviewed (MR1, MR4, MR6 and MR9). Findings include: A review of facility policy "Patient Selection and Pre-Procedure Assessment" dated February 19, 2021, revealed "Purpose. To establish a set of criteria and a screening process to provide safe and effective treatment and patient care in the outpatient setting and in accordance with federal and state regulations. ... Pre-Procedure Physician/LIP/Anesthesia Providers. 1. Confirm patient identification using two identifiers." A review on April 6, 2023, of MR1, admitted January 19, 2023, for an angioplasty procedure under monitored anesthesia care (MAC) revealed	S 552E		

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S 552E	Continued from page 16	S 552E		

the document "Anesthesia Record." There was no documentation the anesthetist had identified the patient prior to the administration of anesthesia.

A review on April 6, 2023, of MR4, admitted October 26, 2022, for a thrombectomy procedure under monitored anesthesia care (MAC) revealed the document "Anesthesia Record." There was no documentation the anesthetist had identified the patient prior to the administration of anesthesia.

A review on April 6, 2023, of MR6, admitted February 6, 2023, for an angioplasty procedure under monitored anesthesia care (MAC) revealed the document "Anesthesia Record." There was no documentation the anesthetist identified the patient prior to the administration of anesthesia.

A review on April 6, 2023, of MR9, admitted December 19, 2022, for an angioplasty procedure under monitored anesthesia care (MAC) revealed the document "Anesthesia Record." There was no documentation the anesthetist identified the patient

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S 552E	Continued from page 17 prior to the administration of anesthesia. An interview conducted on April 6, 2023, at 3:25 PM with EMP2 confirmed the medical records noted above did not contain documentation the patients were identified by the anesthetist prior to the administration of anesthesia.	S 552E		
S 6701	567.1 Principle CHAPTER 567 - ENVIRONMENTAL SERVICES 567.1 Principle The ASF shall have a sanitary environment, properly constructed, equipped and maintained to protect surgical patients and ASF personnel from cross-infection and to protect the health and safety of patients. This REGULATION is not met as evidenced by:	S 6701	An approved Plan of Correction is not on file.	Completion Date: Status: **NO POC** Date:

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(XI) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
	39C0001333	A. BLDG: 00 B. WING:	04/07/2023

NAME OF PROVIDER OR SUPPLIER:	STREET ADDRESS, CITY, STATE, ZIP CODE:
AZURA SURGERY CENTER SOUTH PHILADELPHIA	2412 WEST PASSYUNK AVENUE PHILADELPHIA, PA 19145

STATE LICENSE NUMBER: 24741501

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S 6701	Continued from page 18 Based on a review of facility policies, documents, observation, and interview with staff (EMP), it was determined the facility failed to ensure the surfaces in operating room 1 and operating room 2 were maintained in a sanitary manner and patient care items were stored in a safe and sanitary manner. Findings include: A review of facility policy "Environmental Cleaning" dated February 6, 2021, revealed "Purpose. to maintain a clean and safe environment for patients, staff, and visitors. Policy. The patient care environment throughout the facility will be maintained in a state of cleanliness that meets professional standards in order to protect patients and healthcare personnel from potentially infectious microorganisms." A review of the facility document "Pre & Post Area Cleaning Guidelines," undated, revealed "Clean WEEKLY... All cabinets (inside and out), Wipe down walls, Overhead ceiling track, All vents, All	S 6701		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
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S 6701	Continued from page 19	S 6701		

over-bed tables, All monitor stands/baskets, All monitor stands castors/wheels, IV (intravenous) poles, O2 (oxygen) tanks."

An observation on April 6, 2023, at 10:18 AM in Operating Room 1 (OR1) with EMP1 and EMP6 revealed layers of dust on top of the wall-mounted narcotic box and storage cabinets (high dust). There were layers of dust on the grills of the wall air vents. There was a patient positioning wedge and pillow was stored on the floor.

An observation on April 6, 2023, at 10:46 AM in OR2 with EMP1 revealed layers of dust on top of the wall-mounted narcotic box and on the grills of the wall air vents. The sharps container was covered with layers of dried residue and dust.

An interview conducted on April 6, 2023, at 10:48 AM with EMP1 confirmed layers of dust were found on the narcotic boxes, storage cabinets, air vents and sharps container in OR1 and OR2. EMP1 confirmed the surfaces in the operating rooms were

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S 6701	Continued from page 20 not cleaned in accordance with facility policy.	S 6701		
S 6744	567.41 MAINTENANCE SERVICE - Principle 567.41 Principle The ASF shall be equipped, operated and maintained to sustain its safe and sanitary characteristics and to minimize health hazards in the ASF for the protection of patients and employes. This REGULATION is not met as evidenced by:	S 6744	An approved Plan of Correction is not on file.	Completion Date: Status: **NO POC** Date:

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION (POC)	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION:	(X3) DATE SURVEY COMPLETED:
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S 6744	Continued from page 21 Based on a review of facility policy, observation and interview with staff (EMP), it was determined the facility failed to maintain a safe environment to minimize health hazards for the protection of patients and employees. Findings include: A review of facility policy "Environment of Care Plan" dated August 30, 2021, revealed "Purpose. To promote a safe, functional, and supportive environment within the organization so that quality and safety are preserved. ...Scope. The environment of care is made up of the following: The building or space, including how it is arranged and special features that protect patients, visitors, and staff. Equipment used to support patient care or to safely operate the building or space. People, including those who work within the organization, patients, and anyone else who enters the environment, all of whom have a role in minimizing risks." 1) An observation on April 6, 2023, at 10:58 AM in	S 6744		

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S 6744	Continued from page 22 a patient changing room with EMP1 revealed a large corrugated cardboard box containing packages of sterile surgical gauze stored on top of a chair in the patient changing room. An interview conducted on April 6, 2023, at 10:59 AM with EMP1 confirmed the packages of sterile gauze was still in the original corrugated shipping box. EMP1 further confirmed the surgical gauze should have been removed from the external shipping box inside the supplies receiving area to ensure a clean and safe environment was maintained. 2) An observation on April 6, 2023, at 11:00 AM of the environmental services (EVS) closet with EMP1 revealed boxes of paper towels stored on the floor and stacked on top of one another. The cleaning equipment was stored inside the floor-mounted mop sink on top of a toilet plunger. There was an electrical extension cord stored over the water supply valve. There was no hand sink or hand sanitizer available inside the EVS closet.	S 6744		

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S 6744	Continued from page 23 An interview conducted on April 6, 2023, at 11:02 AM with EMP1 confirmed the supplies were not stored in a proper and sanitary manner inside the EVS closet. EMP1 said "This is a mess. We need to get this equipment out of here." 3) An observation on April 6, 2023, at 11:05 AM of the supplies receiving room with EMP1 revealed the door was open and visible from the hallway leading from the waiting room to the pre and post recovery area. There was a supply cart in the room with several open box cutters stationed on top of the cart. An interview conducted on April 6, 2023, at 11:07 AM with EMP1 confirmed the open box cutters presented a risk of injury to patients, visitors and staff. EMP1 confirmed the supplies receiving room door should have been closed and secured to prevent unauthorized access to the room.	S 6744		